

Response to an Allegation of Interference in Method Approval

Report by a U.S. EPA Scientific Integrity Review Panel

August 13, 2014

Background

The U.S. Environmental Protection Agency (EPA) is dedicated to preserving the integrity of the scientific and scholarly activities it conducts and that are conducted on its behalf. The EPA Scientific Integrity Policy, dated February, 2012, provides principles and standards to ensure scientific integrity in the use, conduct, and communication of science. When this policy is not adhered to, or is circumvented, the robustness of EPA science and the trust in the results of our scientific work can be impacted causing a loss of scientific integrity. Loss of scientific integrity is the result of a deliberate action by an employee that compromises the scientific integrity of the conduct, production, or use of scientific and scholarly activities and assessments. EPA will not tolerate loss of integrity in the performance of scientific and scholarly activities or in the application of science and scholarship in decision making.

Procedures for Resolving Allegations of a Loss of Scientific Integrity

Allegations of the loss of scientific or scholarly integrity are submitted to the EPA's Scientific Integrity Official (ScIO). Three criteria are necessary to establish a loss of integrity:

- 1) There is a significant departure from accepted practices of the relevant scientific or scholarly community,
- 2) The actions causing the loss of integrity are committed intentionally, knowingly or recklessly, and
- 3) The allegation is proven by a preponderance of evidence.

If there is a reasonable basis to believe the allegation may have merit, a Scientific Integrity Review Panel, comprised of the ScIO, the relevant Deputy Scientific Integrity Official (DScIO), and an additional DScIO provide a review of the science and any other relevant information and reach a majority consensus.

Allegation

(b) (6) requested that the U.S. EPA's Office of Inspector General (OIG) investigate EPA's disapproval of an (b) (6) analytical method for measuring oil and grease. (b) (6) claimed that an EPA Office of Water (OW) employee, (b) (6), had a conflict of interest due to his association with (b) (6) competitors and that he purposefully sabotaged the approval. The OIG found that the allegation did not fall under the OIG's purview and referred the case to Dr. Francesca T. Grifo, the EPA ScIO.

Scientific Integrity Review Panel

A Scientific Integrity Review Panel (SIRP) comprised of Dr. Grifo, (b) (6) was convened to review the relevant information on the case. The SIRP found that the (b) (6) charges did not have merit and were not substantiated. The panel found that (b) (6) did not have a conflict of interest with

(b) (6) competitors. (b) (6) did not make decisions for the EPA to approve or disapprove of the (b) (6) method. The SIRP has concluded that the allegation has no basis and, therefore, has dismissed it.

Background on Approved Methods for Measuring Oil and Grease

The Clean Water Act (CWA) establishes the structure for regulating discharges of pollutants into U.S. waters and regulating quality standards for surface waters. The CWA requires a permit, under the National Pollutant Discharge Elimination System (NPDES), to discharge any pollutant from a point source (e.g., from an industrial, municipal, or other point source) into navigable waters.

The Code of Federal Regulations (CFR) at Title 40 part 136 includes approved analytical methods for measuring oil and grease (O&G). These are used for determining compliance with NPDES permit limits and for additional monitoring under the CWA. O&G is a mixture of petroleum-based and vegetable-based chemical compounds that vary depending on the source. Numerical limits for O&G are included in hundreds of thousands of wastewater discharge permits and indirect discharging permits.¹ O&G is a method-defined parameter, meaning that the analytical results obtained are dependent on the method used. EPA has approved two Part 136 O&G methods. These are liquid/liquid extraction (LLE), and gravimetric procedures that use a solvent to extract the O&G.²

Based on questions raised by regulators, States, and laboratories, in 2006, (b) (6) decided to update Method 1664A (an approved O&G measurement method under the Code of Federal Regulations). The updated method would become 1664B in a final rule published in May 2012.³

Background on the (b) (6) Allegation

In 2009, a consultant for (b) (6), contacted (b) (6), in EPA's Office of Water's (b) (6), about the idea of a new method for measuring oil and grease. The (b) (6) method utilizes a membrane filter for extraction (i.e., a solventless extraction process) and infrared absorption to measure O&G. (b) (6) shared some concerns about the (b) (6) method. Later, (b) (6) suggested that (b) (6) could submit it as a new method under the (b) (6). Instead, (b) (6) decided to validate its method through American Society for Testing and Materials (ASTM) as ASTM D7575. In a November 2009 email message, (b) (6) stated, "This is a standalone ASTM method meant for future use worldwide, including non-regulatory purposes in the US. We simply compared the results of the method to an existing method to increase people's comfort level with the new technology we employ. If we've implied that we've met all requirements of 1664, I apologize; it was not our intent. However, ASTM may, in the future, apply for the method to be accepted by the EPA, and that would be the time to raise concerns

¹ From EPA's Notice of Final Decision titled, "Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures; Notice" published in the Federal Register, Volume 78, Number 44, on Wednesday, March 6, 2013, in the Supplementary Information Section, page 14457.

² From EPA fact sheet, "Clean Water Act Analytical Methods Update Rule – Decision on Alternative Oil and Grease Method" <http://water.epa.gov/scitech/methods/cwa/upload/oilgreasefactsheet.pdf>, Office of Water Publication 4303T, dated March 2013.

³ EPA Final Rule titled, "Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures" published in the Federal Register, Volume 77, Number 97, on Friday, May 18, 2012, in the Rules and Regulations section, pp. 29757-29846.

regarding the use of WK23240 [later to become D7575] as an EPA accepted method for regulatory purposes. In addition, it should be clear that this method could never be an ATP for 1664 anyway as it uses a different determinative step (and in fact 1664 specifically disallows the use of infrared)."⁴

(b) (6) had earlier expressed approval of (b) (6) work to revise method 1664A. (b) (6) was a former EPA employee and had managed the EPA Office of Water's (b) (6) for over 30 years. At EPA, (b) (6) had led the development of Method 1664A. In 2008, when (b) (6) work on updating Method 1664A, (b) (6) had responded that the update would be "a good product".⁵

In 2009, (b) (6) submitted information to EPA about ASTM D7575, including a multi-laboratory validation study. The report only contained summary data and, therefore, according to (b) (6), there were no raw data to determine how the validation study report was generated. (b) (6) to call the labs to determine which lab performed which tests to account for inter-laboratory variability.

(b) (6) also contacted U.S. Senator Susan Collins about the company's efforts to have D7575 approved by EPA for regulatory use. Senator Collins' staff met with (b) (6) and EPA in 2010 and 2011 about D7575 and communicated with EPA on the method from 2010 to 2013.

EPA discussed D7575 in its 2010 proposed Methods Update Rule (MUR), where EPA explained that it generally does not approve alternative methods for O&G that use different extraction and/or measurement techniques because it is "unclear how to translate measurements using these alternative methods to those obtained under existing methods for purposes of comparison."⁶

In response to the MUR, EPA received comment and additional data on ASTM D7575, causing EPA to consider revising its regulatory requirements for O&G. In 2011, EPA requested additional comparison testing between D7575 and 1664. The testing was completed in November/December 2011. In December 2011, EPA published a Notice of Data Availability (NODA) on D7575. After reviewing comments to the MUR and NODA and supporting data, EPA issued the final rule on the NODA in March 2013. In a fact sheet on the final rule, EPA stated that it decided to not approve D7575 for use nationwide as an alternative to 40 CFR Part 136 O&G methods, concluding that "this new method is not demonstrated to produce results comparable to those achieved using the current Part 136 methods in the wide ranges of discharges to which oil and grease limitations may apply." However, EPA encouraged permittees to consider whether the method might "be an acceptable alternative to the current methods for their specific discharge" (which would require supporting data and requesting approval as a limited use alternative test procedure using EPA's Alternate Test Procedures).⁷

⁴ From an email message from (b) (6) on November 5, 2009, at 1:18 PM, with subject line, (b) (6) Oil and Grease Method"

⁵ From an email message from (b) (6) on October 6, 2008, at 10:40 AM, with subject line, "RE: Current Method Modifications Issues for 1664A (Oil and Grease) with Recommendations (DRAFT)"

⁶ From EPA's Methods Update Rule titled, "Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures" Proposed Rule published in the Federal Register Notice, Volume 75, Number 184, on Thursday, September 23, 2010, in the Proposed Rules section.

⁷ From EPA Notice of Final Decision titled, "Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures; Notice" published in the Federal Register, Volume 78, Number 44, Wednesday, March 6, 2013, Rules and Regulations, pp. 14457-14461.

Analysis

(b) (6) claims that (b) (6) work on Method 1664B represents a conflict of interest with the (b) (6) method D7575 and that (b) (6) was subject to negative events “led and/or inspired by USEPA’s (b) (6) and associates” that show a “consistent and premeditated attempt to sabotage ASTM D7575 approval.”⁸ (b) (6) claims that (b) (6) inappropriately solicited comments from State Assessors on the NODA.⁹ (b) (6) also claims that (b) (6) inappropriately contacted laboratories that had participated in (b) (6) validation studies for development of D7575, asking them leading questions about the legitimacy of the study.

In 2012, the OIG investigated a complaint about EPA’s evaluation of ASTM D7575. In a July 2013 report titled, “EPA’s Handling of a Proposed Alternative Method for Measuring Oil and Grease in Wastewater Met Requirements But Controls Need to Be Strengthened,”¹⁰ the OIG found that EPA’s handling of the proposed alternative method for measuring oil and grease in wastewater (ASTM D7575) adhered to applicable laws, regulations, policies, procedures, and guidance. Contrary to the (b) (6) claim that EPA sabotaged approval of its method, the OIG found that EPA took appropriate steps to make an informed decision on ASTM D7575, but that management control weaknesses contributed to confusion and delays, and fostered concerns among some stakeholders about fairness, transparency, and preferential treatment for the developer of ASTM D7575. In response to the report, EPA strengthened its procedures for reviewing proposed methods for method-defined analytes, issued procedures for establishing cut-off dates for future Methods Update Rules, and clarified its procedures and policies regarding the two distinct routes through which new methods may be approved in 40 CFR Part 136. With these actions, EPA eliminated the management control weaknesses that the OIG had identified.

The Scientific Integrity Review Panel found no conflict of interest regarding (b) (6) work on developing Method 1664B and EPA’s review of ASTM Method D7575. The work on 1664B started in 2006, several years before (b) (6) approached (b) (6) with questions about what would become ASTM D7575. Also, the two methods (1664B and ASTM D7575) were developed for different purposes. In a November 2009 email message, (b) (6) said that its method was designed as a standalone and that it would not meet all of the requirements of 1664A. According to (b) (6), Method 1664A also quantifies two separate but related parameters: non-polar O&G and hexane extractable material. ASTM Method D7575 does not include procedures for both types of measurements. Also, the two methods measure a method-defined parameter so, by definition, they do not measure the same substance.

(b) (6) claimed that (b) (6) had inappropriate links to non-EPA staff members from (b) (6) competitors or consultants to those competitors. The SIRP found that (b) (6) primary responsibility is to review

⁸ From (b) (6) complaint to EPA OIG Hotline, “ASTM D7575: “Standard Test Method for Solvent-Free Membrane Recoverable Oil and Grease by Infrared Determination” Development and USEPA Non-Approval Chronology/Issues” updated as of July 13, 2013.

⁹ The State Assessors Forum is an Association of Public Health Laboratories (APHL) “volunteer group that discusses regulatory and technical issues related to the assessment of environmental laboratories.” See: http://www.aphl.org/policy/positions/Documents/POL_2012Jul_APHL-Position-Statement_Nongovernmental-Accrediting-Bodies-for-Environmental-Laboratories.pdf

¹⁰ U.S. Environmental Protection Agency Office of the Inspector General Report titled, “EPA’s Handling of a Proposed Alternative Method for Measuring Oil and Grease in Wastewater Met Requirements But Controls Need to be Strengthened” No. 13-P-0317, July 11, 2013.

Alternate Test Procedures and new methods for measurement of analytes currently regulated at Part 136. This requires that (b) (6) interact with co-regulators and members of the environmental regulated community including dischargers, State Assessors, EPA staff and contractors, non-governmental laboratory staff, American Council of Independent Laboratories – Independent Laboratories Institute (ACIL-ILI) members, Standard Methods, ASTM members, and other federal staff (e.g., U.S. Geological Survey). (b) (6) also participates in conferences to maintain contact with stakeholders and to keep informed on new technologies and methods.

(b) (6) alleges a conflict of interest, claiming that (b) (6), an (b) (6) competitor, co-authored EPA Method 1664B. The SIRP found no basis to this claim. (b) (6) did not co-author the method. (b) (6) was a resource, reviewing and commenting on the method, which was acknowledged in the method. Similarly, (b) (6) had acknowledged (b) (6) in the Method 1664A Guidance Document.¹¹

(b) (6) claimed that (b) (6) solicited 269 State Assessors to provide what would turn out to be anonymous negative comments to the NODA docket. According to (b) (6), during a State Assessors' call, (b) (6) was asked about the publication of the NODA and he provided links to the NODA, but did not solicit any comments.

(b) (6) also alleged that (b) (6) distributed erroneous and negative information about ASTM D7575. The SIRP found no basis for this claim. During a State Assessors' call, many of the assessors said that (b) (6) had been promoting D7575 as an EPA Part 136 method. (b) (6) told the assessors that D7575 was not an approved Part 136 method. (b) (6) also claimed that (b) (6) provided non-public USEPA information to non-USEPA personnel that are employees of (b) (6) competitors. However, (b) (6) did not provide specific information to support this claim.

Regarding (b) (6) contact with laboratories that had participated in the validation studies for D7575, (b) (6) had asked (b) (6) to review the validation study report and had instructed him to call the laboratories to get an idea of which laboratory performed which tests, in order to account for inter-laboratory variability. (b) (6) documented his conversations with the laboratories and the information that they provided. (b) (6) claimed that (b) (6) had harassed or threatened the laboratories. However, (b) (6) did not provide, nor did the SIRP evaluation uncover, any evidence to support that claim.

(b) (6) claimed that (b) (6) has a conflict of interest because of his involvement in the development of Method 1664B and that his actions show a "consistent and premeditated attempt to sabotage ASTM D7575 approval." However, (b) (6) did not have the authority to approve or disapprove D7575 or any other method. The decision to approve or not approve a method is made by the EPA Administrator. Any methods submitted to the (b) (6) program are reviewed by laboratory professionals both internal and external to EPA. Note that ASTM method D7575 was never submitted for review by application through the (b) (6) program. (b) (6) was not responsible for the decision to not propose the method for inclusion at 40 CFR Part 136 in the FR notice that was published on September 23, 2010. Nor was he the author of or member of the internal EPA work group for the NODA that was published in the FR on December 14, 2011, nor for the Notice of Final Decision that was

¹¹ US EPA, "Analytical Method Guidance for EPA Method 1664A Implementation and Use (40 CFR part 136)", Office of Water No. 4303, EPA/821-R-00-003, February 2000.

published in the FR on March 6, 2013. The work on the U.S. EPA final decision on the NODA, which reversed the previous NODA stance on ASTM D7575, was done by a work group without (b) (6) involvement.

The SIRP's assessment also indicated that (b) (6) has no financial interest or political interest associated with Method 1664A, Method 1664B, or ASTM Method D7575, nor with any company that submits methods for review under EPA's (b) (6) program. (b) (6) developed Method 1664A, not (b) (6). (b) (6), initiated the work to update Method 1664A and assigned the work to (b) (6). However, there is no evidence that (b) (6) has any personal financial interest either in Method 1664 or in any of the companies that offer the method in their laboratory services.

(b) (6) also claimed that EPA approved Method 1664B for nation-wide use without providing data to show that it was validated and effective. However, Method 1664B did not require validation data because the method only provides clarifications on allowed and disallowed modifications to this method, which measures a specific Part 136 method-defined analyte. In other words, the method clarifies the sections in the method that a laboratory would be permitted to change without approval by the EPA. Furthermore, the method was appropriately proposed and promulgated through rulemaking.

Conclusion

(b) (6) claimed that regulatory approval of its ASTM Method D7575 for Oil and Grease was sabotaged by (b) (6), who according to the company, has an inherent conflict of interest. The EPA Scientific Integrity Review Panel, convened to review this allegation, evaluated the allegation and found no basis for the (b) (6) complaint. The panel's analysis found that (b) (6) does not have any conflict of interest with Method 1664A, Method 1664B, ASTM Method D7575, or with any other method or company that submits methods for review under the (b) (6) program. The panel's analysis did not reveal inappropriate contacts between (b) (6) and non-EPA personnel during the EPA review of ASTM D7575. (b) (6) was not in a position to make decisions regarding EPA's approval or disapproval of (b) (6) method.

The EPA Scientific Integrity Review Panel, convened to examine this allegation, has concluded that the allegation has no basis and, therefore, has dismissed it.